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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/778,002	02/11/2004	Birgit Oppmann	DX0935KB	3603

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LEGAL DEPARTMENT
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EXAMINER
HAYES, ROBERT CLINTON

ART UNIT	PAPER NUMBER
1649	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/778,002	OPPMANN ET AL.	
	Examiner	Art Unit	
	Robert C. Hayes, Ph.D.	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 November 2006 & 05 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31-40 and 46-48* is/are rejected.

7)☐ Claim(s) *41-45 and 49* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/7/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group III (cancelled claims 1, 2 & 4; as it relates to the human IL-B60 & CLF-1 polypeptide complexes) in Paper NO: 11/8/06 is acknowledged. The traversal is on the ground(s) that "the subunits of this protein complex share significant amino acid identity [with Group I], and therefore, should not be a serious burden to search". This is not found persuasive because a serious search burden does exist for searching different sequences which are otherwise unique, as exemplified by their unique SEQ ID NOs; especially as it relates to searching combinations of two SEQ ID NOs: together, and for the reasons previously made of record. Thus, the non-coextensiveness of the search and examination for each group would constitute an undue burden on the examiner to search and consider all the separable groups with their recognized divergent subject matter. The requirement is still deemed proper and is therefore made FINAL.

Claims 31-35 (in part; as it relates to nonelected SEQ ID NOs: 4 & 13) are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions, the requirement having been traversed in Paper No: 11/8/06.

The requirement is still deemed proper and is therefore made FINAL.

This application contains claims 31-35 (as it relates to SEQ ID NOs: 4 & 13) drawn to an invention nonelected with traverse in Paper No. 11/8/06. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Allowable Subject Matter

2. Claims 41-45 & 49 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 U.S.C. § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 46-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

No proper antecedent basis nor conception in context with that described within the specification at the time of filing the instant application exists on page 88 of the specification for the recitations of "cholingeric modulators" (i.e., as it relates to claims 47 & 48), or for generic "expression of neuromodulators by [generic] neurons" (i.e., as it relates to claim 46). In contrast, page 88 of the specification describes use of one specific population of cholinergic neurons (i.e., sympathetic cholingereic neurons), which showed "induction of different neuromodulators... [which include] CCK, VIP, SP and SOM" when stimulated with IL-B60/CLF-1. Induction of any generic "neuromodulator by neurons" is not contemplated; thereby, constituting new matter.

Induction of any putative "cholinergic modulators" is not contemplated; thereby, constituting new matter. In contrast, "upregulation" of CCK, VIP, SP and SOM after stimulation of cholinergic sympathetic neurons with IL-B60/CLF-1 is contemplated and described on page 88 of the specification.

4. Claims 31-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses on pages 6-7 that various short non-overlapping fragments of IL-B60 and CLF-1 are encompassed by the instant invention. Pages 11-12 of the specification disclose fusion polypeptides encompassed by the instant invention. Polypeptide variants are then described on page 37 to include "proteins or peptides having substantial amino acid sequence identity...", which "include species, polymorphic, allelic variants". No written description of any other species (except for mouse), or any other polymorphic or allelic variants sequences are provided in the instant specification. Page 64 then invites others to "determine the critical residues in IL-B60-IL-B60 receptor interactions". And that "[h]elices A and D are most important in receptor interaction". However, Table 2 indicates that helix D is 33 amino acids in length at the C-terminal end of hIL-B60, and that helix A is 18 amino acids at the N-terminal end of hIL-B-60. In other words, even these two required regions in IL-B60 are much greater than the "at least 6 amino acids... recited in the instant claims"; thereby, making the claims not

reasonably commensurate in scope with that taught by the instant specification. Nevertheless, the specification fails to provide any other disclosure on what critical amino acids would constitute a functional polypeptide complex or a functional CLF-1 complex of any type. Likewise, the claims do not require that any additional "cytokine complexes" possess any particular biological activity, nor any particular conserved structure, nor other disclosed distinguishing feature. To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. Thus, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus of "cytokine complexes" because one skilled in the art can not structurally visualize or predict what critical amino acid residues would structurally characterize the genus of IL-B60/CLF-1 complex polypeptides, as encompassed by the claims; thereby, not reasonably meeting the written description requirements of 35 U.S.C. 112, first paragraph. See MPEP 2163.

3. Claims 31-40 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while enabling for compositions comprising the human IL-B60/ human CLF-1 polypeptide complex consisting SEQ ID NOs: 2 & 12, respectively, does not reasonably provide enablement for any biologically functional equivalent forms of putative cytokine complexes with little recited structural and functional characteristics. The specification does not enable any person

skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The names "soluble cytokine complex" or functional variants or derivatives thereof do not sufficiently characterize and enable the full scope of the polypeptide complexes encompassed by the current claim language, because the inclusion of amino acid "substitutions, deletions, insertions, inversions", or biological functional equivalents as disclosed on pages 37-39 & 41 of the specification within the definition of such sets forth little structural and no definable functional characteristics. Importantly, the specification does not teach which particular amino acids are critical for a generic IL-B60/CLF-1 complex polypeptide's function; nor how to distinguish IL-B60/CLF-1 complex variants encompassed by the instant invention from any different IL-B60/CLF-1 complex-related polypeptide that possesses none of the desired functions of the instant invention; especially as it relates to only "at least 6 amino acids..." being required to form each component of the claimed soluble cytokine complex. Therefore, any such broadly claimed polypeptides without sufficient definable structural and functional characteristics would be expected by the skilled artisan to encode inactive proteins. For example, Rudinger states on page 3 that "it is impossible to attach a unique significance to any residue in a sequence. A given amino acid will not by any means have the same significance in different peptide sequences, or even in different positions of the same sequence". Rudinger further states on page 6 that "the significance of particular amino acid sequences for different aspects of biological activity cannot be predicted *a priori* but must be determined from case to case by painstaking experimental study". Therefore, the lack of guidance provided in the specification as to what minimal structural requirements are necessary for a functional IL-B60/CLF-1 complex polypeptide would

prevent the skilled artisan from determining whether any random modification or mutation or truncation to the disclosed human IL-B30 of SEQ ID NO: 2 and the human CLF-1 polypeptide of SEQ ID NO: 12 could be made which retains the desired function of the instant invention, because any random mutation or modification or truncation manifested within an IL-B60/CLF-1 complex variant protein would be predicted to adversely alter the biologically active 3-dimensional conformation of the native IL-B60/CLF-1 complex without requiring undue experimentation to determine otherwise.

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for this Group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert C. Hayes, Ph.D.
March 26, 2007

ROBERT C. HAYES, PH.D.
PRIMARY EXAMINER